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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,590	01/08/2001	Stewart Russell Jurgensen	P-4993	5633

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EXAMINER	
TRAN, MY CHAU T	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 03/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Office Action Summary	Application No. 09/756,590	Applicant(s) JURGENSEN ET AL.
	Examiner My-Chau T. Tran	Art Unit 1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 30 December 2002 .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22,24-31 and 33-36 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-22,24-31 and 33-36 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☒ The proposed drawing correction filed on 30 December 2002 is: a)☒ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's amendment filed 12/30/02 in Paper No. 10 is acknowledged and entered. Claims 23 and 32 are canceled. Claims 1, 5-7, 19, 21, and 31 are amended. Claims 1-22, 24-31, and 33-36 are pending.

Drawings

2. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 12/30/02 has been approved. A proper drawing correction or corrected drawings and the drawing informalities noted in Paper No. 10, mailed on 8/28/02 are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance.

3. Claims 1-22, 24-31, and 33-36 are treated on the merit in this Office Action.

Withdrawn Rejections

4. The previous rejections under 35 USC 112, second paragraph for claims 1-18, 21, 23, 32, and 35 have been withdrawn in view of applicant's amendment of claims 1, 5-7, 19, 21, and 31.

5. The previous rejections under 35 USC 102(b) and 35 USC 103(a) have been withdrawn in view of applicant's amendments of claims 1, 5-7, 19, 21, and 31. However, upon further consideration, the following new grounds of rejection are made as follows. Therefore, this Office action is a non-final rejection.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New Rejections – Necessitated by Amendment

7. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. The phrase "sample components to be harvested from said sample" in Claim 1 lines 4-5 is vague and indefinite because it is unclear as to the basis for this limitation in the claim method of separating components from a sample.

9. Claims 1, 5-7, 13, and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Levine et al. (US Patent 5,635,362).

The presently claimed invention recites a method of separating components from sample material. The method comprises the method step of providing a sample material in a sampling container, wherein the sampling container having a focusing device with a passage for receiving and elongating layers of sample component. The method step of providing one antibody in the sampling container, and mixing the antibody with the sample, wherein the antibody has an affinity for binding with one substance of the sample. The method step of centrifuging the container and sample at sufficient G forces to separate components of the sample and forcing a target component from the sample into the passage.

Levine teaches the device and method for the analyses of blood sample for the presence or absence of a target analyte or analytes that are caused to settle in a predetermined location in a transparent tube (col. 1, lines 9-18). The assay method disclosed comprised of adding the sample to the tube so as to allow the density-marker/binding material capture body or bodies to incubate and intermix with the sample sufficiently to cause any target analytes present in the sample to couple with and be captured by their complementary partners on the density-markers before centrifugation (col. 3, lines 35-54). The tube is a transparent tube with a float/insert (col. 6, lines 10-17; fig. 1, 2, and 3). The float/inserts is cylindrical and movable and it has a specific gravity such that it would sink through the red cell layer in the centrifuged blood sample or come to rest in an area where the density-marker/binding material capture body or bodies also come to rest (col. 2, lines 46-52). Both of the float/inserts can be used to capture analyte (col. 8, lines 25-26). The blood sample is centrifuged in the tube and the density-marker/binding material capture body or bodies with different specific gravity will form bands that settle into the restricted space between the float/insert in the tube (col. 2, lines 38-67; col. 3, lines 1-12). The density-marker/binding material captures body or bodies are beads that are coupled with a capture binding material such as antibodies (col. 3, lines 13-34). The target analyte of interest are lymphocyte blood cells (white blood cells) or hermatopoietic progenitor blood cells (stem cell or fetal cell), which can be found in bone marrow, peripheral blood or cord blood (col. 9, lines 51-53; col. 10, lines 51-57). The method of Levine anticipated the claimed method.

10. Claim 1-7, 13, and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine et al. (US Patent 5,635,362) in view of Levine et al. (US Patent 5,393,674).

The presently claimed invention recites a method of separating components from sample material. The method comprises the method step of providing a sample material in a sampling container, wherein the sampling container having a focusing device with a passage for receiving and elongating layers of sample component. The method step of providing one antibody in the sampling container, and mixing the antibody with the sample, wherein the antibody has an affinity for binding with one substance of the sample. The method step of centrifuging the container and sample at sufficient G forces to separate components of the sample and forcing a target component from the sample into the passage.

Levine et al., which is now refer to as Levine #1, teaches the device and method for the analyses of blood sample for the presence or absence of a target analyte or analytes that are caused to settle in a predetermined location in a transparent tube (col. 1, lines 9-18). The assay method disclosed comprised of adding the sample to the tube so as to allow the density-marker/binding material capture body or bodies to incubate and intermix with the sample sufficiently to cause any target analytes present in the sample to couple with and be captured by their complementary partners on the density-markers before centrifugation (col. 3, lines 35-54). The tube is a transparent tube with a float/insert (col. 6, lines 10-17; fig. 1, 2, and 3). The float/inserts is cylindrical and movable and it has a specific gravity such that it would sink through the red cell layer in the centrifuged blood sample or come to rest in an area where the density-marker/binding material capture body or bodies also come to rest (col. 2, lines 46-52). The blood sample is centrifuged in the tube and the density-marker/binding material capture body or bodies with different specific gravity will form bands that settle into the restricted space between the float/insert in the tube (col. 2, lines 38-67; col. 3, lines 1-12). The density-

marker/binding material captures body or bodies are beads that are coupled with a capture binding material such as antibodies (col. 3, lines 13-34). The target analyte of interest are lymphocyte blood cells (white blood cells) or hermatopoietic progenitor blood cells (stem cell or fetal cell), which can be found in bone marrow, peripheral blood or cord blood (col. 9, lines 51-53; col. 10, lines 51-57).

Levine #1 differs from the instant invention in failing to include in the method step of removing the target component and the float includes ribs.

Levine et al. (US Patent 5,393,674), which is refer to as Levine #2, teach a device and method for centrifuging blood into its constituent layers similar to the instant invention and that of Levine #1 (col. 1, lines 7-14; fig. 1 and fig. 4). The method of Levine #2 comprise of centrifuging the blood sample in a glass tube, which contains a float (col. 2, lines 61-68 to col. 3, lines 1-12). The float is formed with a core portion which has a through bore (channel) (ref. #7 of fig. 1), and an annular sleeve portion (ribs) (ref # 11 of fig. 1) that expands and contracts responsive to the magnitude of dynamic forces imposed on the float during performance of the sample centrifugation (col. 2, lines 15-19; col. 4, lines 6-14). The cells and components of the buffy coat layer are expanded linearly in the narrow bore channel in the float and thus can be easily harvested (col. 3, lines 13-15). The method includes harvesting the target cells from the float bore (ref. #7 of fig. 5) with a needle (col. 4, lines 55-57; fig. 5).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Levine #1 by incorporating the method step of removing the target component as taught by Levine #2 because it would provide the advantage of performing multiple methods such as cell concentration, assay, and harvesting in a unitary

sealed tube (Levine #2: col. 1, lines 41-57). This would also reduce exposure of contaminated blood to the technician and the disposal of contaminated blood would be in a stable, inert environment. The ribs of the float would provide a ten fold expansion of the white cell and platelet layers when performing the cell harvesting with the tube-float combination (Levine #2: col. 2, lines 50-60). Therefore, one would have had reasonable expectation of success of incorporating the method step of removing the target component into the method of Levine #1 because both Levine #1 and Levine #2 teaches the method of cell separation.

11. Claims 1, 5-13, and 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine et al. (US Patent 5,635,362) in view of Van Vlasselaer (US Patent 5,474,687).

The presently claimed invention recites a method of separating components from sample material. The method comprises the method step of providing a sample material in a sampling container, wherein the sampling container having a focusing device with a passage for receiving and elongating layers of sample component. The method step of providing one antibody in the sampling container, and mixing the antibody with the sample, wherein the antibody has an affinity for binding with one substance of the sample. The method step of centrifuging the container and sample at sufficient G forces to separate components of the sample and forcing a target component from the sample into the passage.

Levine et al., which is now refer to as Levine #1, teaches the device and method for the analyses of blood sample for the presence or absence of a target analyte or analytes that are caused to settle in a predetermined location in a transparent tube (col. 1, lines 9-18). The assay method disclosed comprised of adding the sample to the tube so as to allow the density-

marker/binding material capture body or bodies to incubate and intermix with the sample sufficiently to cause any target analytes present in the sample to couple with and be captured by their complementary partners on the density-markers before centrifugation (col. 3, lines 35-54). The tube is a transparent tube with a float/insert (col. 6, lines 10-17; fig. 1, 2, and 3). The float/inserts is cylindrical and movable and it has a specific gravity such that it would sink through the red cell layer in the centrifuged blood sample or come to rest in an area where the density-marker/binding material capture body or bodies also come to rest (col. 2, lines 46-52). The blood sample is centrifuged in the tube and the density-marker/binding material capture body or bodies with different specific gravity will form bands that settle into the restricted space between the float/insert in the tube (col. 2, lines 38-67; col. 3, lines 1-12). The density-marker/binding material captures body or bodies are beads that are coupled with a capture binding material such as antibodies (col. 3, lines 13-34). The target analyte of interest are lymphocyte blood cells (white blood cells) or hermatopoietic progenitor blood cells (stem cell or fetal cell), which can be found in bone marrow, peripheral blood or cord blood (col. 9, lines 51-53; col. 10, lines 51-57).

Levine differs from the instant invention in failing to specifically disclose the density, size and type of the beads.

Van Vlasselaer teaches a method of density-adjusted cell sorting which uses cell type-specific binding agents such as antibodies and lectins linked to carrier particles (beads) to impart a different density to cell populations in blood allowing the cells to be separated during centrifugation (col. 1, lines 13-19). The carrier particles (beads) include polystyrene latex and organic polymer such as polyvinyl compounds (col. 11, lines 45-53). The particle size is of 0.1

to 5.0 micron (col. 11, lines 45-67 to col. 12, lines 1-3). The density is adjusted 1.06 g/ml in order to ensure reproducibility and accuracy of the cell separation (col. 13, lines 22-25).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the density beads of Levine with those density beads of Van Vlasselaer. One of ordinary skill would be motivated because both Levine and Van Vlasselaer teaches methods of providing accurate and reproducible cell separation layers. Levine teaches for cell separation that different density beads are needed to produce different bands in the tube to permit rapid screening and identification (Levine: col. 4 lines 11-25). Further, Van Vlasselaer disclosed that there is a number of commercially available beads can be use in the method of cell separation (Van Vlasselaer: col. 11, lines 45-53). The choice of one particular type of beads is dependent on the availability and accessibility. Therefore, one would have known to substitute the density beads of Levine with density beads of Van Vlasselaer to separate the desired cells. One would have had reasonable expectation of success using the beads of Van Vlasselaer with the method of Levine because both use the similar method to achieve cell separation.

12. Claims 19-22, and 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine et al. (US Patent 5,393,674) in view of Van Vlasselaer (US Patent 5,474,687).

The presently claimed invention recites a method of harvesting a target component from a sample. The method comprises the method step of providing a sample in a sampling tube, wherein the sampling tube contains a float that fit within the sampling tube. The float has an axial passage for receiving and elongating layers of blood constituents to be harvested from said sample. A method step of mixing the sample with a particulate carrier (bead) having a density of

about 1.0 to 1.06 g/cc, size of about 4 microns to 5 microns and containing antibody having a binding affinity for a specific constituent. A method step of centrifuging the tube and sample at sufficient G forces to move the float toward one end of the tube and to force the target component from the sample into the through passage. A method step of removing the target component from the through passage.

Levine et al. (US Patent 5,393,674) disclose a method for harvesting target cells from centrifuged sample of blood contained in a tube which also contains a cylindrical float having a through passage for receiving and elongating layers of blood cell components to be harvested from the sample, the float having an axial constant outer diameter which ensures that the float fits snugly in the tube (claim 1). The method steps of centrifuging the blood, tube, and float at sufficient G forces to move the float toward one end of the tube and forcing the blood cell components to settle in said through passage (claim 1). The cells and components of the buffy coat layer are expanded linearly in the narrow bore channel in the float and thus can be easily harvested (col. 3, lines 13-15). The method includes harvesting the target cells from the float bore (ref. #7 of fig. 5) with a needle (col. 4, lines 55-57; fig. 5).

The method of Levine et al. (US Patent 5,393,674) does not expressly disclose that the method includes having a particulate carrier that contains antibody having a binding affinity for a specific sample constituent and having a density of about 1.0 to 1.06g/cc and size of about 4 to 5 microns.

Van Vlasselaer teaches a method of density-adjusted cell sorting which uses cell type-specific binding agents such as antibodies and lectins linked to carrier particles (beads) to impart a different density to cell populations in blood allowing the cells to be separated during

centrifugation (col. 1, lines 13-19). The carrier particles (beads) include polystyrene latex and organic polymer such as polyvinyl compounds (col. 11, lines 45-53). The particle size is of 0.1 to 5.0 micron (col. 11, lines 45-67 to col. 12, lines 1-3). The density is adjusted 1.06 g/ml in order to ensure reproducibility and accuracy of the cell separation (col. 13, lines 22-25). Further, Van Vlasselaer discloses a method of density gradient centrifugation and affinity cell separation in which the cells are separated based on the different densities of the cell types in a mixture (col. 10, lines 22-23 and 51-54). When density adjusted cell sorting is applied to a cell mixture, which overlaid onto a customized density gradient contained within a cell-trap centrifugation tube, a single centrifugation step allows for substantial enrichment of a cell type of interest from any cell mixture (col. 11, lines 6-10). The method comprise of cell type-specific binding agents (antibodies) conjugated to heavy carrier particles (beads) with specificity for antigens expresses by the cell (col. 64-66). A variety of such cell type-specific binding agents may be used to target specific cell types in blood and includes antibodies (col. 11, lines 17-24). Many of these antibodies are commercially available in a form already conjugated to various types of particles (col. 11, lines 24-26).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a particulate carrier that contains antibody having a binding affinity for a specific sample constituent and having a density of about 1.0 to 1.06g/cc and size of about 4 to 5 microns as taught by Van Vlasselaer in the method of Levine et al. (US Patent 5,393,674). One of ordinary skill in the art would have been motivated to include a particulate carrier that contains antibody having a binding affinity for a specific sample constituent and having a density of about 1.0 to 1.06g/cc and size of about 4 to 5 microns in the method of

Levine et al. (US Patent 5,393,674) for the advantage of providing for a rapid and high yield procedures to enrich for cell of interest and processing a complete sample would not requires no specialized instrumentation (Van Vlasselaer: col. 3, lines 22-28 and 43-45). Since both Levine et al. (US Patent 5,393,674) and Van Vlasselaer disclose the method of blood cell separation by centrifugation (Levine et al. (US Patent 5,393,674): col. 1, lines 7-14; fig. 1 and fig. 4; Van Vlasselaer: col. 2, lines 59-63).

13. Claims 31, and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine et al. (US Patent 5,393,674) in view of Van Vlasselaer (US Patent 5,474,687).

The presently claimed invention recites a method of harvesting a target component from a whole blood sample. The method comprises the method step of providing a sample in a sampling tube, wherein the sampling tube contains a float that fit within the sampling tube. The float has an axial passage for receiving and elongating layers of blood constituents to be harvested from said sample. A method step of mixing the sample with a first carrier beads having a density of about 1.0 to 1.06 g/cc and coating of the first antibody having a binding affinity for a specific constituent; and a second carrier beads having a coating of the second antibody having a binding affinity for white blood cells. A method step of centrifuging the tube and sample at sufficient G forces to move the float toward one end of the tube and to force the target component from the sample into the through passage. A method step of removing the target component from the through passage.

Levine et al. (US Patent 5,393,674) disclose a method for harvesting target cells from centrifuged sample of blood contained in a tube which also contains a cylindrical float having a

through passage for receiving and elongating layers of blood cell components to be harvested from the sample, the float having an axial constant outer diameter which ensures that the float fits snugly in the tube (claim 1). The method steps of centrifuging the blood, tube, and float at sufficient G forces to move the float toward one end of the tube and forcing the blood cell components to settle in said through passage (claim 1). The cells and components of the buffy coat layer are expanded linearly in the narrow bore channel in the float and thus can be easily harvested (col. 3, lines 13-15). The method includes harvesting the target cells from the float bore (ref. #7 of fig. 5) with a needle (col. 4, lines 55-57; fig. 5).

The method of Levine et al. (US Patent 5,393,674) does not expressly disclose that the method includes having a particulate carrier that contains antibody having a binding affinity for a specific sample constituent and having a density of about 1.0 to 1.06g/cc.

Van Vlasselaer teaches a method of density-adjusted cell sorting which uses cell type-specific binding agents such as antibodies and lectins linked to carrier particles (beads) to impart a different density to cell populations in blood allowing the cells to be separated during centrifugation (col. 1, lines 13-19). The carrier particles (beads) include polystyrene latex and organic polymer such as polyvinyl compounds (col. 11, lines 45-53). The particle size is of 0.1 to 5.0 micron (col. 11, lines 45-67 to col. 12, lines 1-3). The density is adjusted 1.06 g/ml in order to ensure reproducibility and accuracy of the cell separation (col. 13, lines 22-25). Further, Van Vlasselaer discloses a method of density gradient centrifugation and affinity cell separation in which the cells are separated based on the different densities of the cell types in a mixture (col. 10, lines 22-23 and 51-54). When density adjusted cell sorting is applied to a cell mixture, which overlaid onto a customized density gradient contained within a cell-trap centrifugation tube, a

single centrifugation step allows for substantial enrichment of a cell type of interest from any cell mixture (col. 11, lines 6-10). The method comprise of cell type-specific binding agents (antibodies) conjugated to heavy carrier particles (beads) with specificity for antigens expresses by the cell (col. 64-66). A variety of such cell type-specific binding agents may be used to target specific cell types in blood and includes antibodies (col. 11, lines 17-24). Many of these antibodies are commercially available in a form already conjugated to various types of particles (col. 11, lines 24-26).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a particulate carrier that contains antibody having a binding affinity for a specific sample constituent and having a density of about 1.0 to 1.06g/cc as taught by Van Vlasselaer in the method of Levine et al. (US Patent 5,393,674). One of ordinary skill in the art would have been motivated to include a particulate carrier that contains antibody having a binding affinity for a specific sample constituent and having a density of about 1.0 to 1.06g/cc in the method of Levine et al. (US Patent 5,393,674) for the advantage of providing for a rapid and high yield procedures to enrich for cell of interest and processing a complete sample would not requires no specialized instrumentation (Van Vlasselaer: col. 3, lines 22-28 and 43-45). Since both Levine et al. (US Patent 5,393,674) and Van Vlasselaer disclose the method of blood cell separation by centrifugation (Levine et al. (US Patent 5,393,674): col. 1, lines 7-14; fig. 1 and fig. 4; Van Vlasselaer: col. 2, lines 59-63).

Response to Arguments

14. Applicant's arguments with respect to claims 1-22, 24-31, and 33-36 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct
March 8, 2003

PADMASHRI PONNALURI
PRIMARY EXAMINER